



2025 KOL Event

EscharEx[®] VLU Phase III and Commercial Opportunity



Robert J. Snyder, DPM



John C. Lantis II, MD



Vickie R. Driver, DPM

January 8, 2025 | Nasdaq: MDWD

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This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act and other securities laws, including but not limited to the statements related to the commercial potential of our products and product candidates, the anticipated development progress of our products and product candidates, and our expected cash runway. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. Forward-looking statements are not historical facts, and are based upon management’s current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management’s expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Important factors that could cause such differences include, but are not limited to the uncertain, lengthy and expensive nature of the product development process; market acceptance of our products and product candidates; the timing and conduct of our studies of our product candidates; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; our expectations regarding future growth, including our ability to develop new products; risks related to our contracts with BARDA; our ability to maintain adequate protection of our intellectual property; competition risks; and the need for additional financing. These and other significant factors are discussed in greater detail in MediWound’s annual report on Form 20-F for the year ended December 31, 2023, filed with the Securities and Exchange Commission (“SEC”) on March 21, 2024, and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound’s current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law

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KOL Event - Agenda

Presenter	Topic
Ofer Gonen, CEO	Welcome & Introduction
Robert J. Snyder, DPM, MBA, MSc	EscharEx Phase II Data Summary
Vickie R. Driver, DPM, MS, FACFAS	VALUE Phase III Study Overview
Barry Wolfenson, EVP Strategy	US DFU/VLU Market and Debridement Utilization
John C. Lantis II, MD	EscharEx – An Exceptionally Attractive Commercial Opportunity
KOL Panel	Expert Q&A Session

MediWound - Company Highlights



Validated enzymatic technology platform

14 successful clinical trials
120+ peer-reviewed publications
Key approvals: FDA/EMA/JPN



Diversified portfolio

NexoBrid® - Eschar removal for severe burns
EscharEx® - Debridement for chronic wounds¹



Significant commercial opportunity

NexoBrid® - 2024 revenue of **\$20M**
EscharEx® - Targets a **\$2.5B U.S. market²**
Challenges a \$360M+ dominant product



Strategic global collaborations

Vericel, Mölnlycke, Kaken, Solvatum, EIC, MiMedx, BARDA, DoD, PolyMedics, BSV



Solid balance sheet with strong investor base

Cash of \$44M³
Runway through profitability



cGMP certified sterile manufacturing facility

6x scale-up to support global demand to be fully operational by YE 2025

Multi-Billion Dollar Portfolio

Commercial

NexoBrid®

Disruptive therapy for burn care



Indication: Eschar removal of deep partial and full thickness burns

Classification: Orphan biological drug

Target users: Hospitalized patients

Development status: FDA/EU/JP approved

TAM^{2,3} (U.S.): **\$300M+**

Pipeline

EscharEx®

Next-Gen enzymatic therapy for wound care¹



Targeted indication: Debridement of chronic/hard-to-heal wounds

Classification: Biological drug

Target users: Patients in all wound care settings

Development status: Three successful Phase 2 studies
Phase 3 for VLU set for Q1 2025
Preparations for DFU Phase 2/3 are currently underway

TAM (U.S.): **\$2.5B**

Objectives for Today

- **EscharEx Phase III Study: Designed for Success**

Building on the robust results of our Phase II study, we will share the design and key endpoints of the upcoming Phase III study to demonstrate why we are confident in its success

- **EscharEx: A Transformative Market Opportunity**

The market potential for EscharEx is both substantial and unique, given that the current competitor:

a) Is the sole product available in this category

b) Has achieved significant commercial success despite limited supporting data



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EscharEx Phase II Data Summary

Robert J. Snyder, DPM, MBA, MSc, CWSP, FFPM RCPS
Chief Medical Officer, MediWound
Dean, Professor and Director of Clinical Research, Barry University
School of Podiatric Medicine



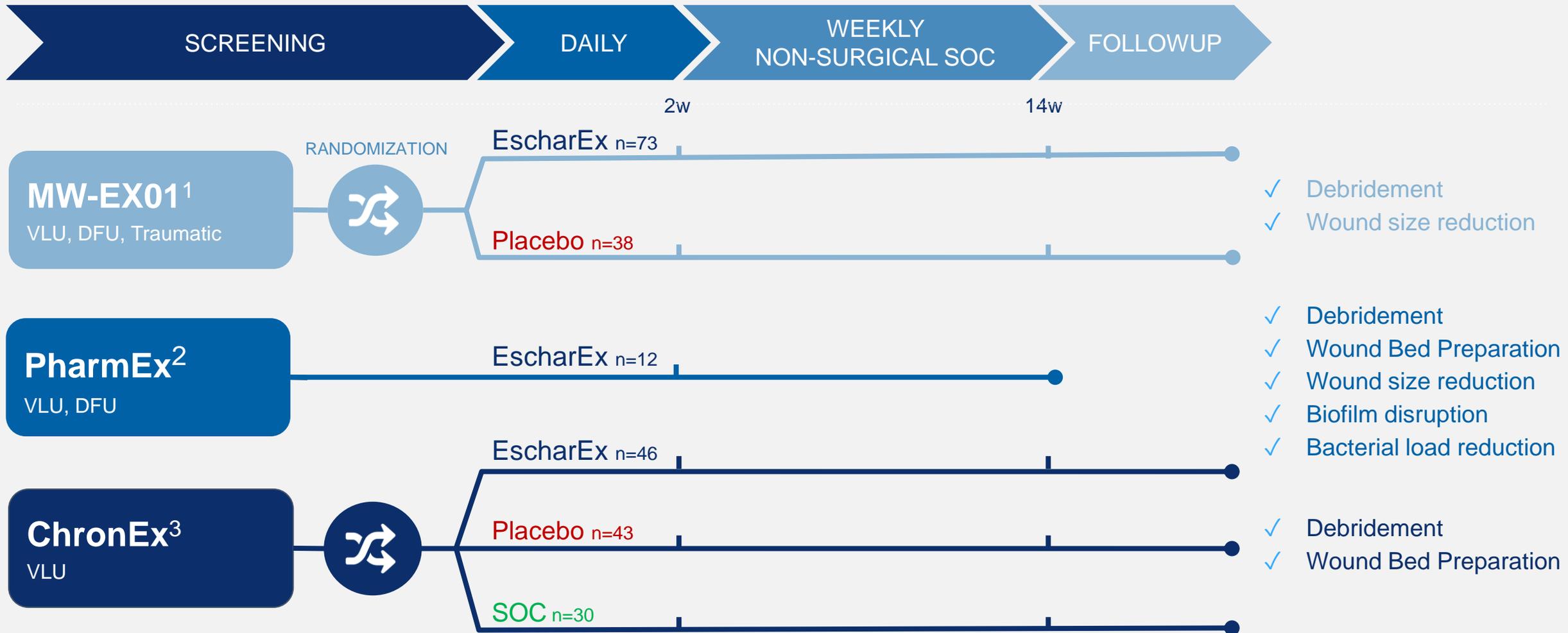
Robert J. Snyder, DPM

EscharEx[®]: Bromelain Based Debridement

- Investigational biological product in **late-stage clinical development for VLU**
- Mixture of proteolytic enzymes enriched with **bromelain**, derived from the stem of **pineapple plant**
- Utilizes the **same active ingredient** as NexoBrid[®], FDA/EMA approved for eschar removal in burns
- **Phase 2 trials** (VLU, DFU, traumatic ulcers) showed superiority over placebo hydrogel & non-surgical standard of care^{1,2,3} in **debridement** of non-viable tissue, and promotion of **granulation** tissue in patients with **chronic wounds**

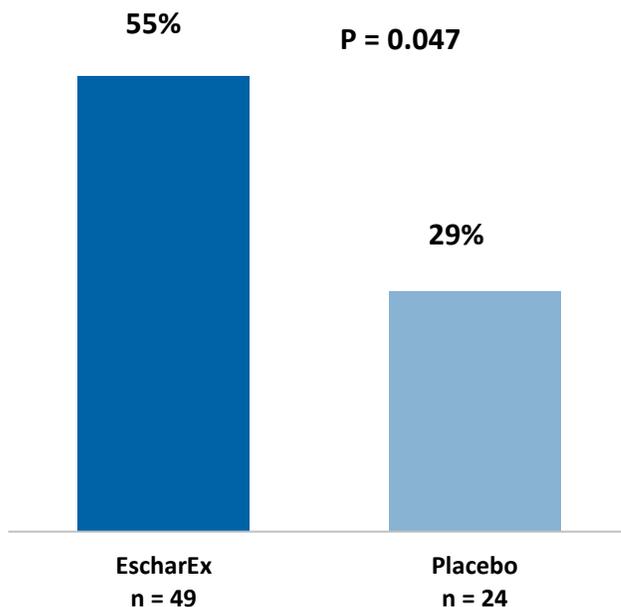


Robust and Consistent Results in Three Phase 2 Studies



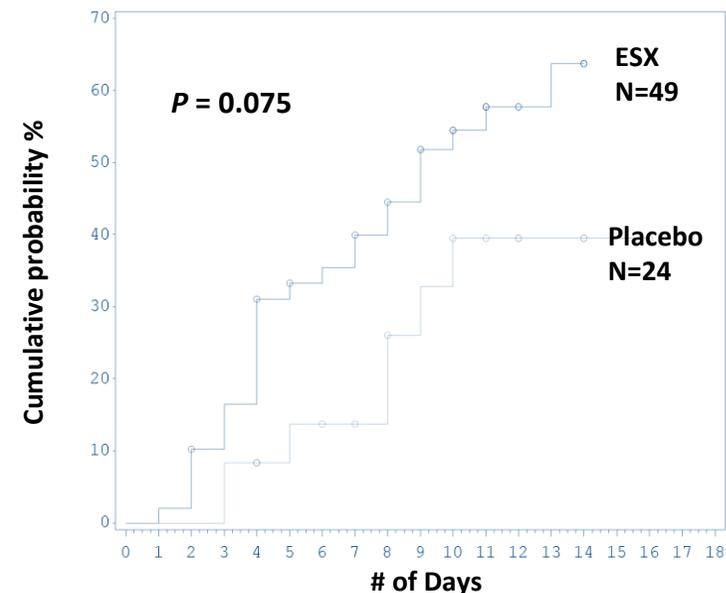
MW-EX01: Primary Endpoint Significantly Met

Incidence of complete debridement
(VLU, DFU, Traumatic ulcers)



Significantly higher incidence of complete debridement

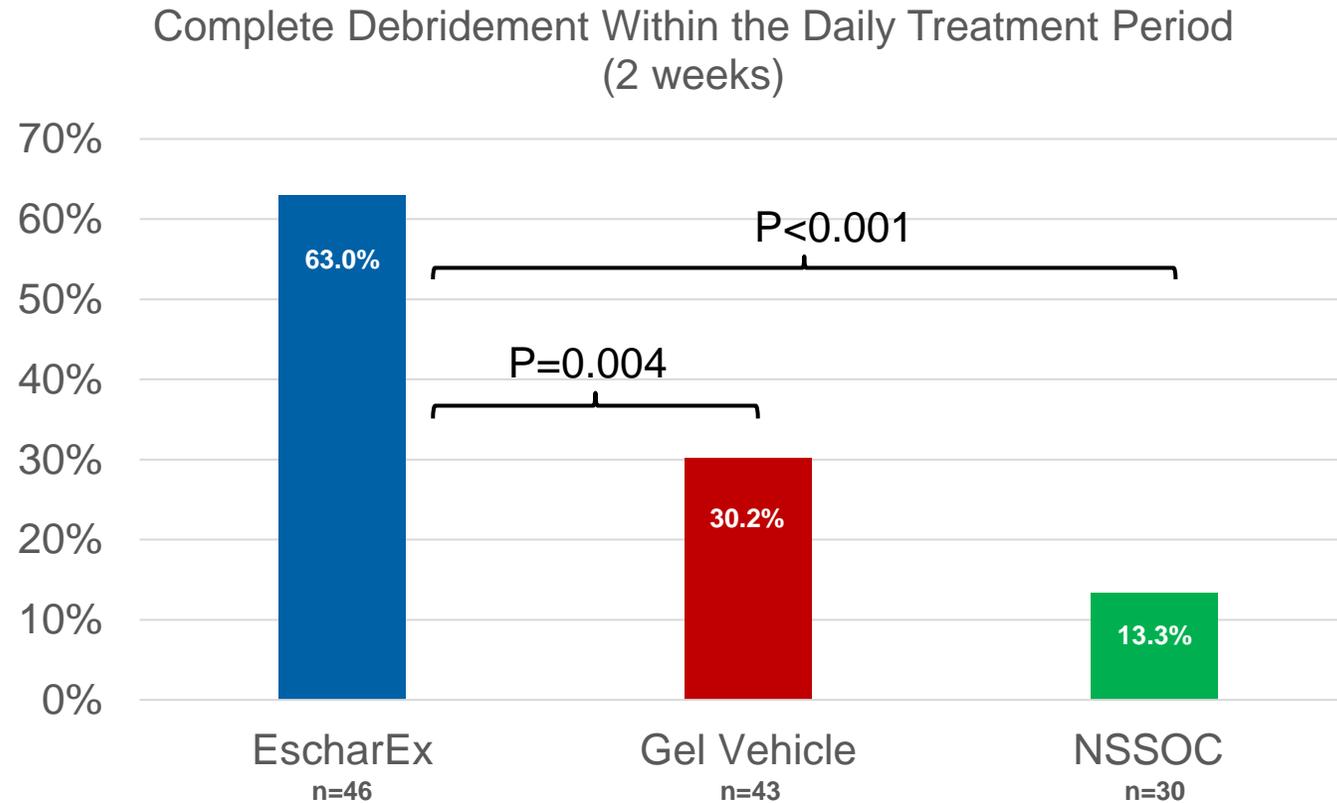
Time to complete debridement
(VLU, DFU, Traumatic ulcers)



Shorter time to achieve complete debridement

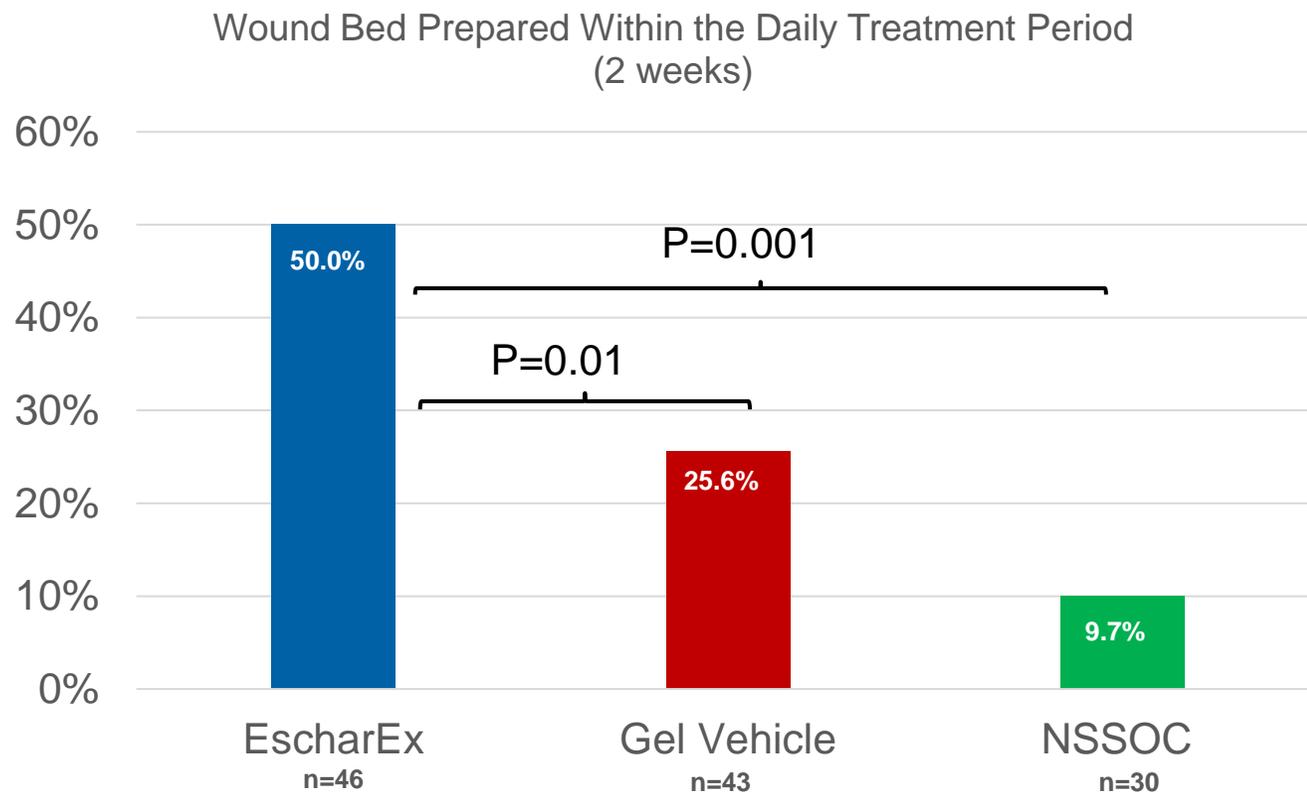
Over 90% of the patients who completed debridement with EscharEx[®] were debrided within 7 days (4-5 daily applications)

ChronEx: Incidence of Complete Debridement



EscharEx[®] achieved a significantly higher incidence of complete debridement compared to both placebo (primary end point) and NSSOC

ChronEx: Incidence of Wound Bed Prepared

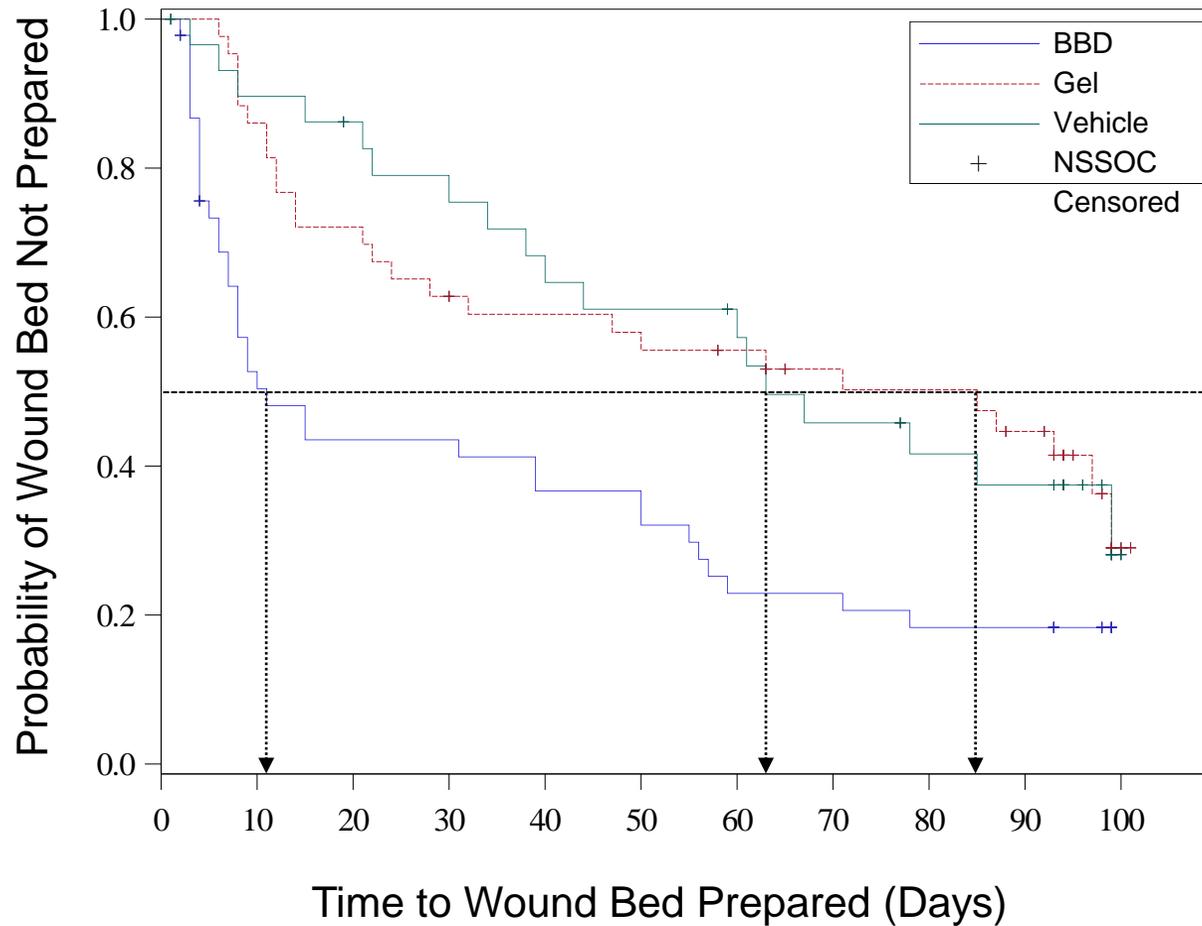


Wound Bed Prepared (WBP)

Complete debridement and complete cover of the wound bed with granulation tissue

The incidence of WBP on EscharEx was significantly higher vs. the Gel Vehicle and NSSOC within the daily visits period (2 weeks)

ChronEx: Faster Time to Wound Bed Preparation



Estimated median time to WBP

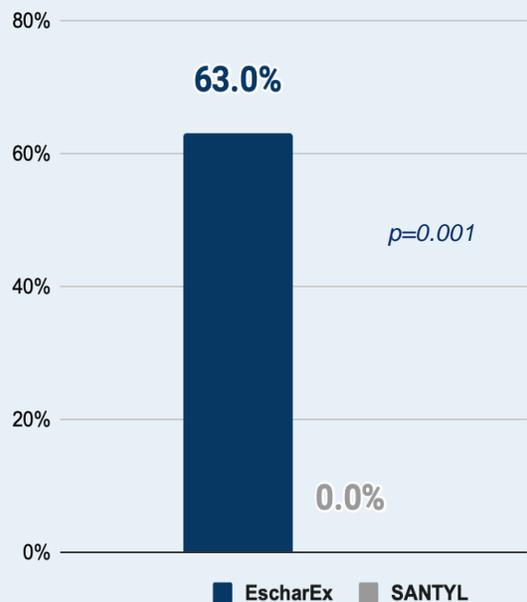
EscharEx®: 11 days vs.

- NSSOC: 63 days (P=0.01)
- Gel Vehicle: 85 days (P=0.004)

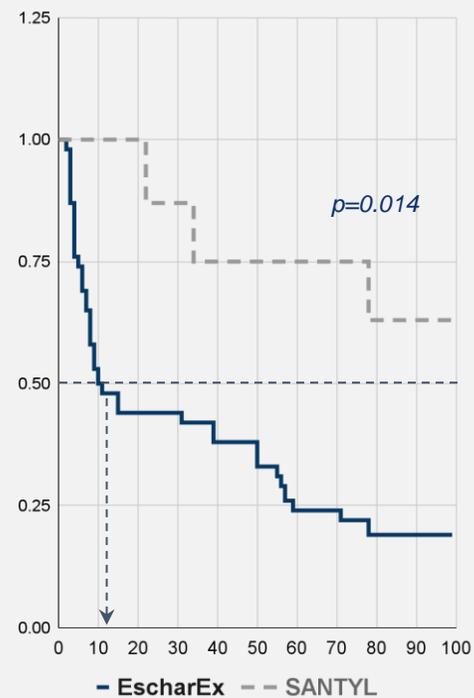
EscharEx achieved wound bed prepared significantly faster than Gel Vehicle and NSSOC

ChronEx: EscharEx[®] vs. SANTYL[®] Head-to-Head Data

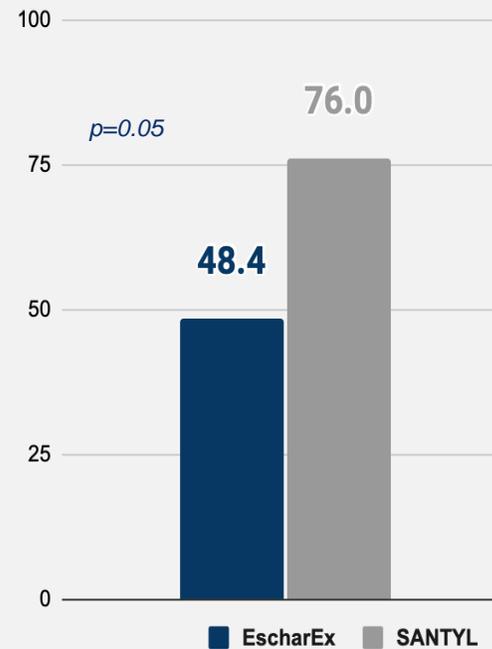
Incidence of complete debridement in 2 weeks



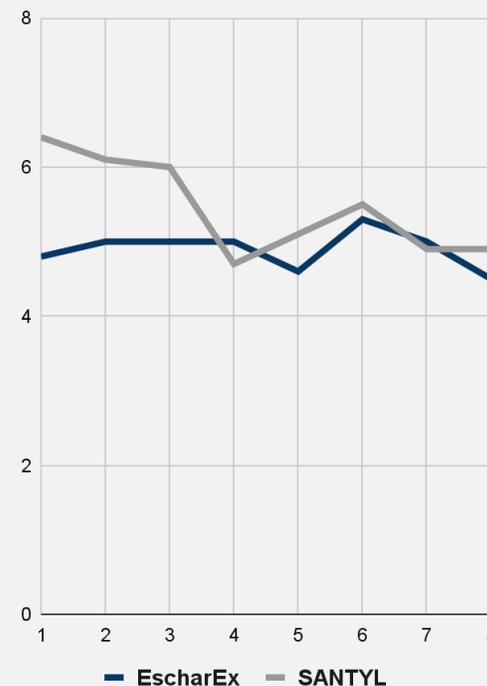
Median time to WBP



Time to wound closure



Patient reported pain



PharmEx: EscharEx Surpasses Traditional Debridement

WOUNDS

ORIGINAL RESEARCH

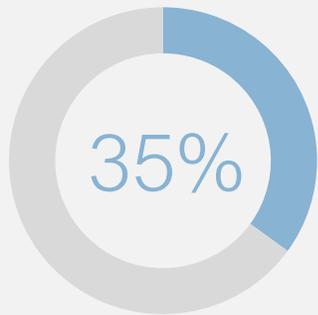
An Open-Label, Proof-of-Concept Study Assessing the Effects of Bromelain-Based Enzymatic Debridement on Biofilm and Microbial Loads in Patients With Venous Leg Ulcers and Diabetic Foot Ulcers



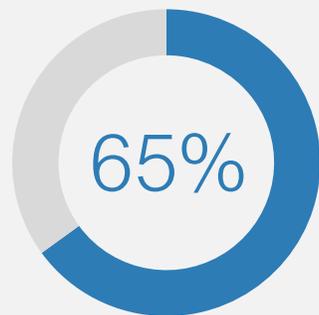
[Robert J. Snyder](#), [Adam J. Singer](#), [Cyaandi R. Dove](#), [Stephen Heisler](#), [Howard Petusevsky](#), [Garth James](#), [Elinor deLancey Pulcini](#), [Aya Ben Yaakov](#), [Lior Rosenberg](#), [Edward Grant](#), [Yaron Shoham](#)

Keywords

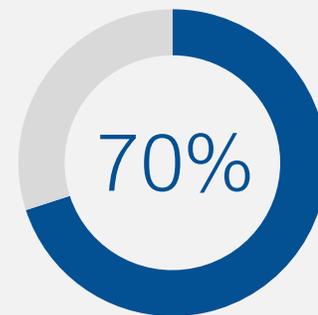
[Bacteria](#)
[Biofilm](#)
[Bromelain](#)



Wound size reduced by end of two-week follow-up



Bioburden reduction by end of treatment



Complete debridement within 8 applications



Biofilm reduced for patients positive at baseline

Takeaways: EscharEx[®] is a 'Triple Threat' for WBP

Across 3 Phase 2 studies, EscharEx has demonstrated its efficacy in:

- Promoting rapid debridement
- Stimulating granulation tissue
- Effectively disrupting biofilm and eliminating planktonic bacteria



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VALUE Phase III Study Overview

Vickie R. Driver, DPM, MS, FACFAS, FAWWC
Professor, Washington State University, School of Medicine
Founding Chair, Wound Care Collaborative Community
Professor-affiliate, Barry University (USA)
Fellow, Royal College of Physicians and Surgeons-Glasgow



Vickie R. Driver, DPM

EscharEx® Planned VALUE Phase 3 Study in VLU Patients

STUDY OBJECTIVES

To assess safety and efficacy of EscharEx compared to placebo in VLU patients



STUDY DESIGN

A global (US, EU, ROW), randomized, double blind, adaptive design study in VLU patients

Two arms: EscharEx vs. placebo, 1:1 ratio

Sample size: 216 VLU patients

Study design:

- Daily treatment: Up to 8 applications over 2 weeks, followed by 10 weeks of standardized wound management
- Active wound closure (CTP/ autograft) for patients reaching WBP
- 12 weeks durability follow-up for patients that reached wound closure

Pre-defined interim assessment: Conducted after 67% of patients completed the initial 12-week period



ENDPOINTS

Co-primary:

Incidence of complete debridement

Incidence of complete wound closure

Secondary:

Incidence of 100% granulation tissue

Time to complete debridement

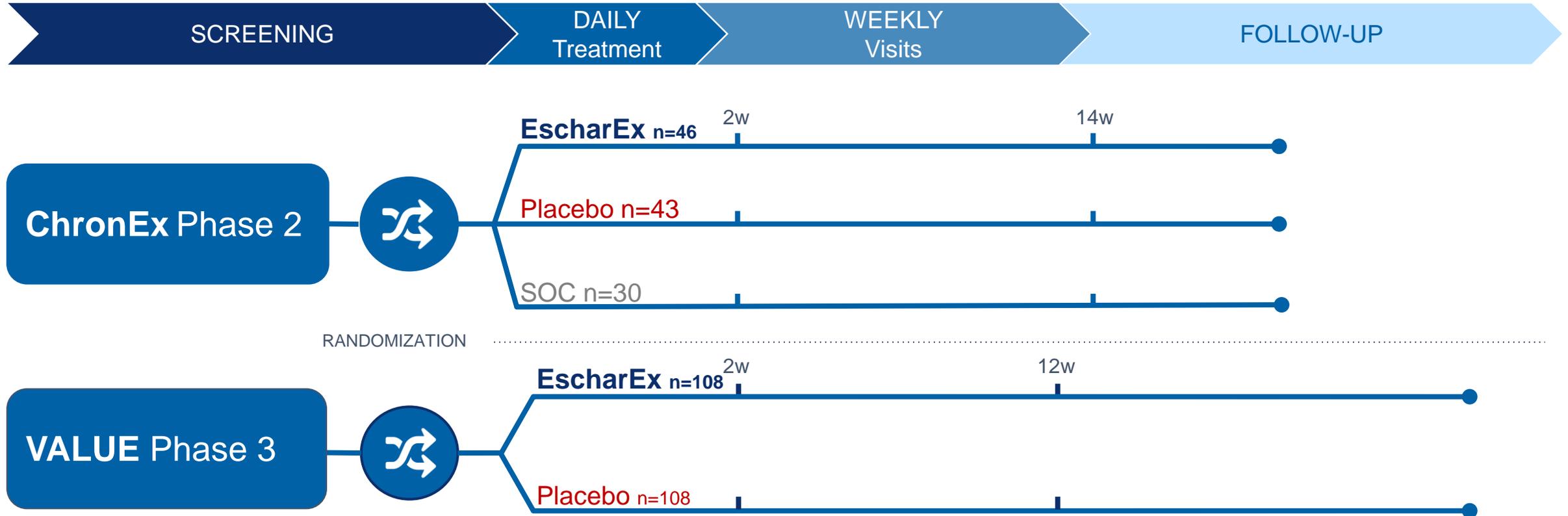
Time to complete wound closure

Change in wound area

Safety:

Safety & tolerability | ECG | Change in pain |
Wound infection rates | Immunogenicity

Phase 3 Study: Proven Phase 2 Design with Key Enhancements



- ✓ Sample size based on ChronEx data vs placebo
- ✓ Interim analysis for sample size re-assessment
- ✓ Mandatory active wound closure (CTP/autograft)
- ✓ Standardized dressings

Projected Superiority in Incidence of Complete Debridement

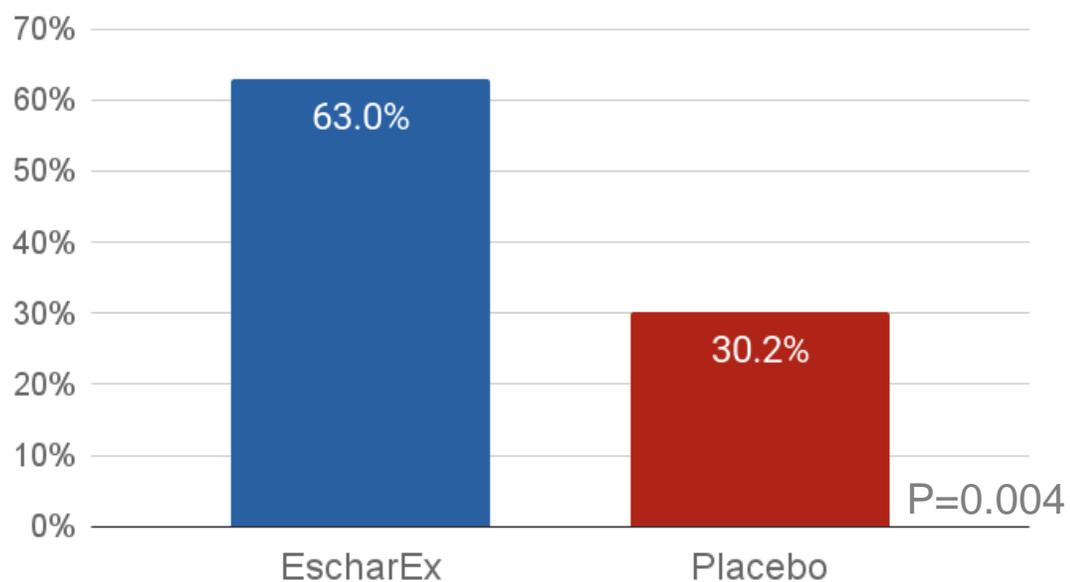
ChronEx Phase 2



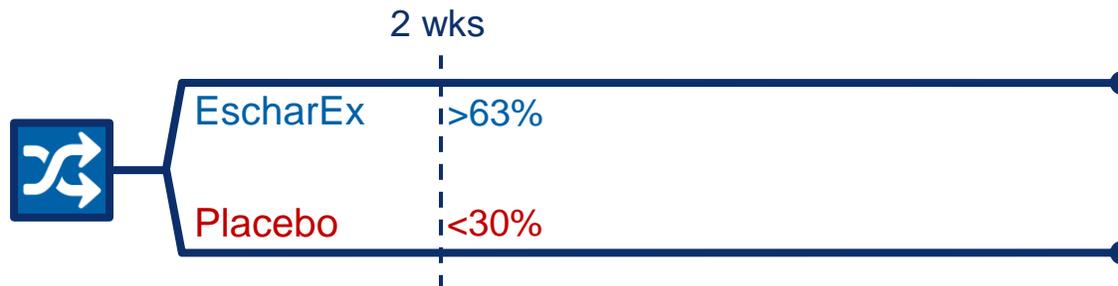
VALUE Phase 3

1st co-primary endpoint

Complete Debridement Within the Daily Treatment Period (2 Weeks)



Projected outcome



- **Same endpoint**
Incidence of complete debridement
- **Larger sample size**
89 → 216
99% power

Projected Superiority in Incidence of Wound Closure

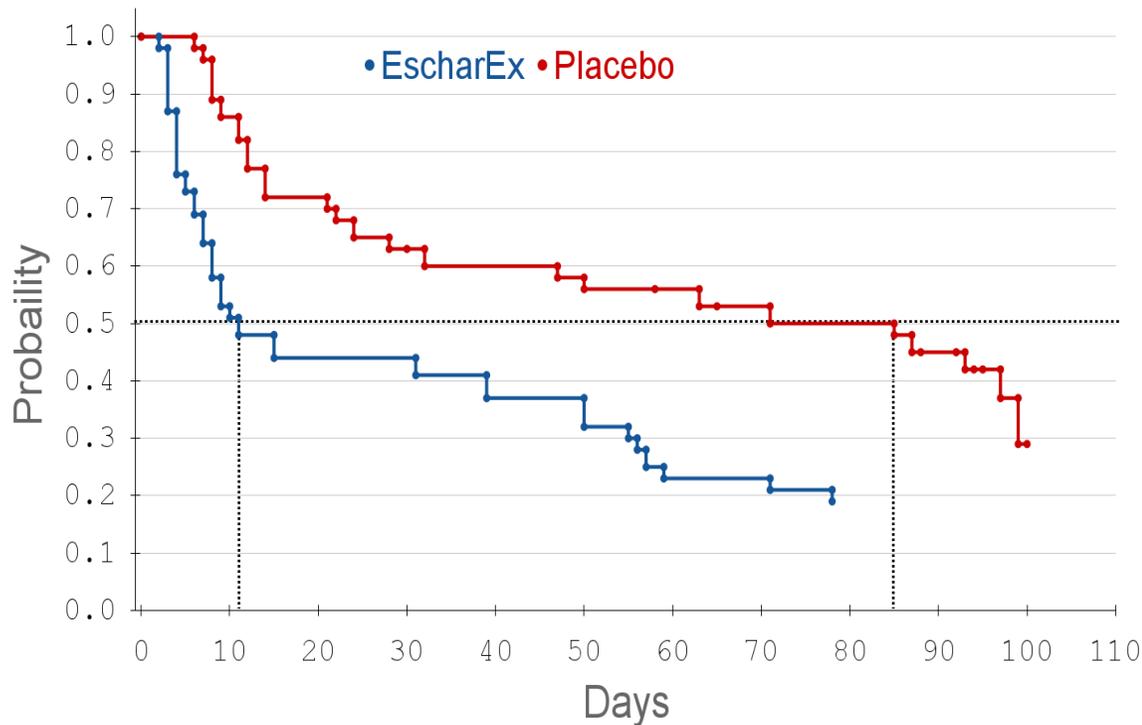
ChronEx Phase 2



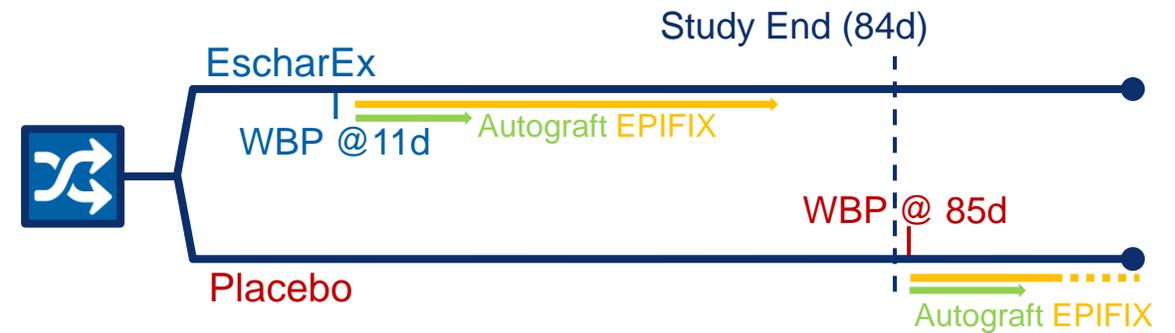
VALUE Phase 3

2nd co-primary endpoint

Time to wound bed prepared



Projected outcome



- **Favorable endpoint**
Mandatory active closure, with projected 74-day head start
- **Standardized treatment**
Throughout study period
- **Larger sample size**
89 → 216
>85% power
Interim analysis for sample size re-assessment

Phase 3 Study Designed to Win

- **Derisked**

Same API as NexoBrid

14/14 successful clinical trials in NexoBrid and EscharEx

- **Proven study design with improvements**

Based on successful ChronEx Phase 2 Trial

Shorter trial period lowers the likelihood of placebo achieving wound bed preparation

Increased sample size (89 → 216) ensures >85% power

- **Favorable protocol**

Mandatory active wound closure after wound bed preparation favors EscharEx, as it achieves wound bed preparation much faster

Added interim assessment for sample size adjustment

- **Standardized treatment**

Collaborations with Solventum, Mölnlycke, and MiMedx help reduce variability and enhance consistency in wound management



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US DFU/VLU Market and Debridement Utilization

Barry J. Wolfenson, MBA
Executive Vice President, Strategy & Corporate Development

VLU and DFU – The Basics

VLU Venous Leg Ulcers



Underlying pathology - Chronic venous insufficiency

Affects - Lower leg or ankle

Ulcer characteristics - Large, shallow ulcers; moderate/severe pain

Prevalence – 2% of population age 65+
1.5M+ new cases annually (US)

Complications - Infection, pain, disability

Societal impact - Substantial healthcare burden, low QoL

Management - Debridement, wound bed preparation, compression therapy, control inflammation and infection, promote healing

DFU Diabetic Foot Ulcers



Underlying pathology - Diabetes (Type I/II)

Affects - Mostly bottom of the foot

Ulcer characteristics - Small, deep ulcers; varying pain levels

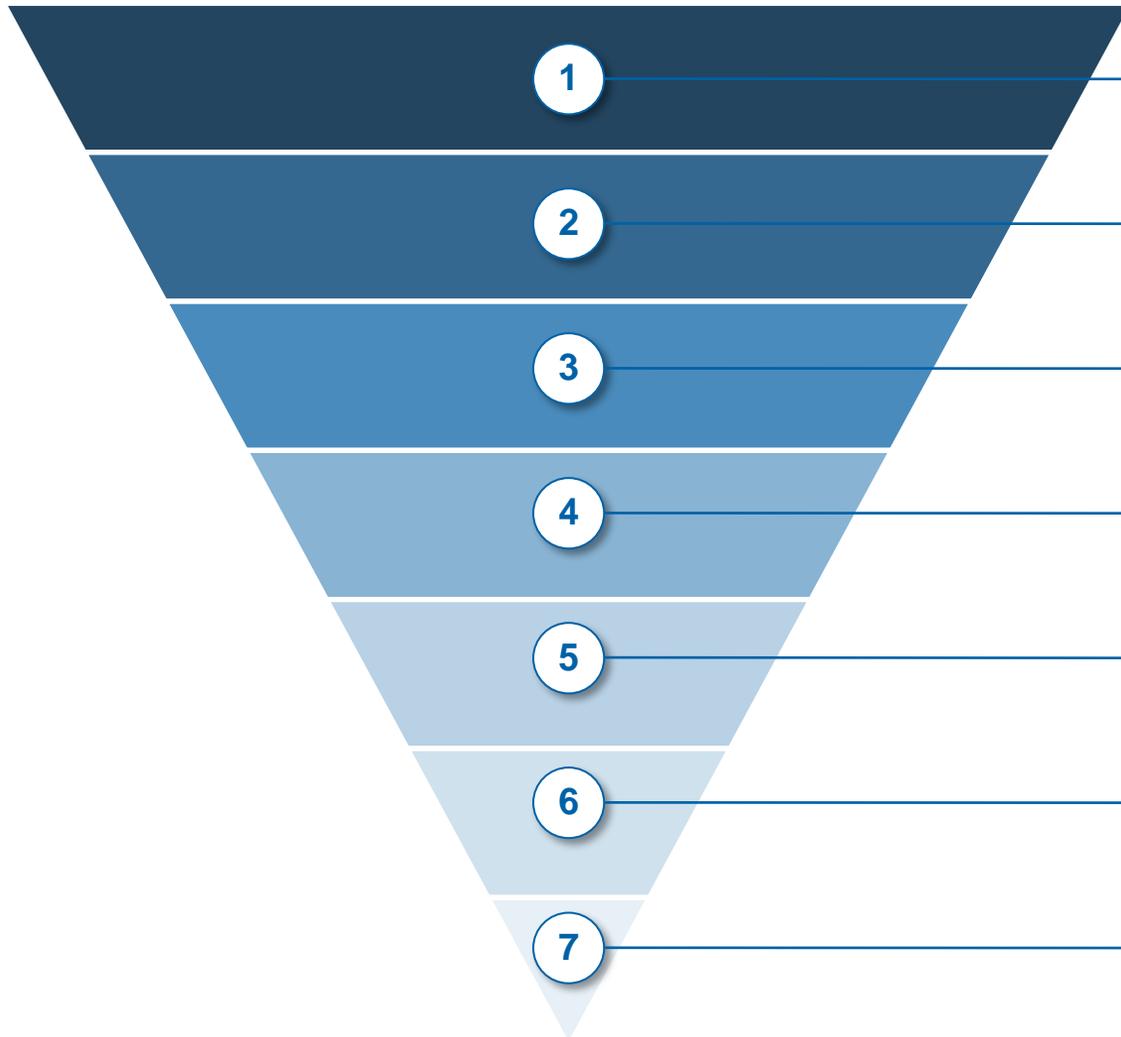
Prevalence - 25-34% of diabetics develop DFU in their lifetime
2.2M+ new cases annually (US)

Complications - Infection, sepsis, amputation, death

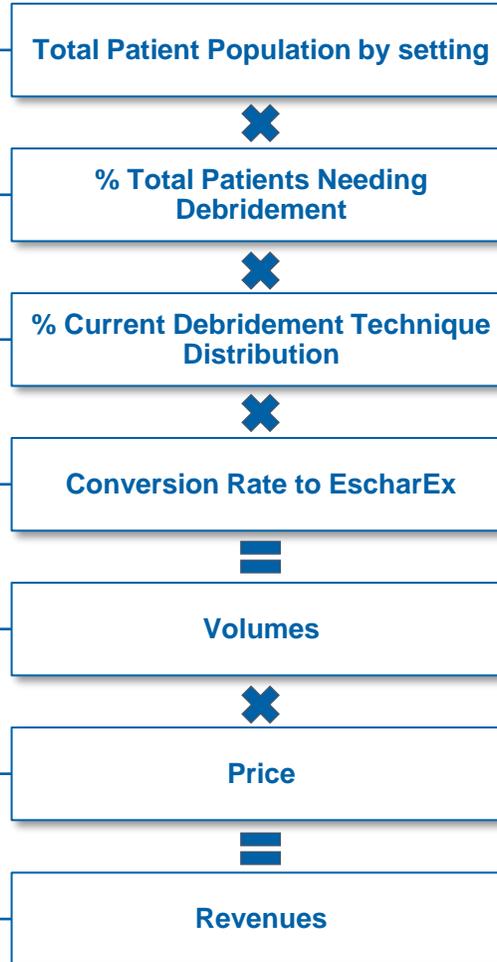
Societal impact - Substantial healthcare burden, low QoL

Management - Debridement, wound bed preparation, offload pressure, moist wound healing, control inflammation and infection, promote healing

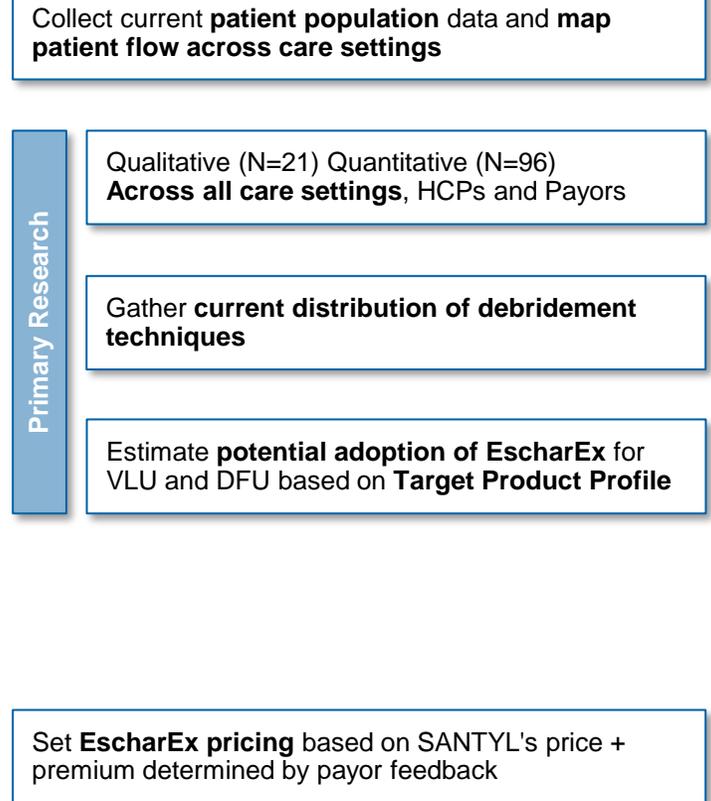
Revenue Model & Research Methodology



Revenue Model

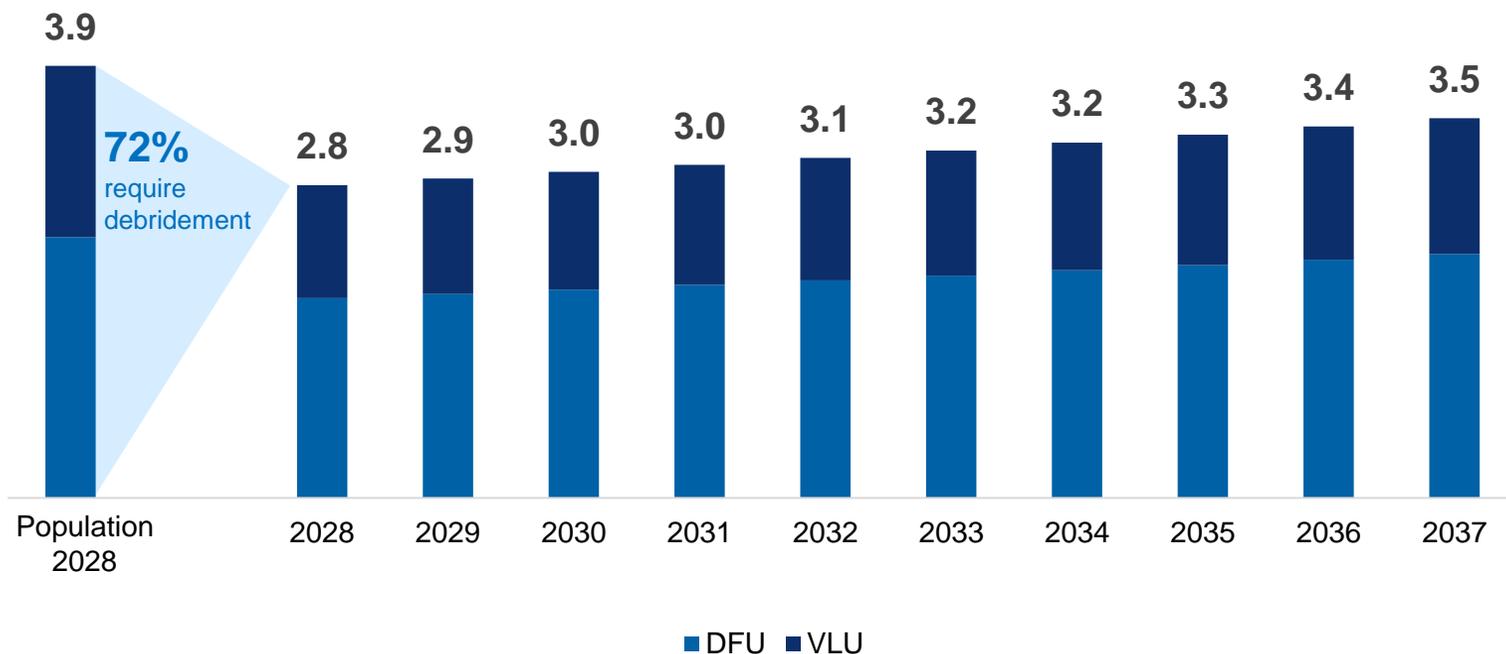


Research Methodology

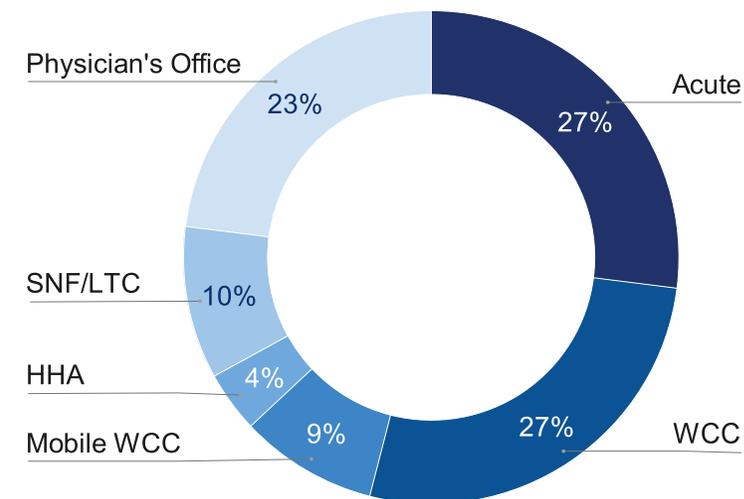


Patients and Care Settings in the Total Addressable Market

Total Addressable Market , '28-'37, [M]



TAM Distribution by Setting



Estimated Pricing Assumptions

Component	Estimated Pricing	Methodology
Price anchor	\$740 (Current SANTYL average cost per patient)	SANTYL dosing calculator (santyl.com) combined with published clinical trial data, triangulated with primary market research and 2 additional 3 rd party data sources
EscharEx premium adjustment	15%	Primary reasearch with payors
EscharEx final price	\$851	

This estimate focuses solely on the two co-primary endpoints and does not yet consider additional Health Economic Outcome Results, which could support a higher price premium compared to SANTYL. E.g., number of in-clinic visits, wound infection, complications etc.

Detailed pricing & Market Access analysis planned for 2025

Strong Clinician Interest in Faster, Easier Debridement



Acute

EscharEx is valued for its ability to expedite **complete debridement** and **wound granulation**, thereby **optimizing DRG reimbursement** and **minimizing readmission risks**.



SNF/LTC

EscharEx is valued for its **ability to shorten debridement treatment** and **outperform SANTYL**. In SNFs, it is particularly valued for **optimizing bundled payment reimbursements**, improving margins, and reducing readmission rates.



WCC

EscharEx is valued for its **efficiency in debridement, promotion of wound granulation**, and ease of use, **making it ideal for continued at-home treatment** by patients or caregivers with limited wound care skills. Importantly, it **expedites the application of tissue substitute**.



Physician Office

Physicians show strong interest towards EscharEx due to its **superior wound healing** and **faster debridement**, which helps **reduce the overall disease burden** for patients, as long as the price remains competitive with SANTYL. Importantly, it **expedites the application of tissue substitute**.



Mobile WCC

Physicians highly value EscharEx for its **ease of use**, which enhances home treatment adherence and **improves overall clinical outcomes** compared to SANTYL. Importantly, it **expedites the application of tissue substitute**.



HHA

EscharEx is valued for its **faster debridement, superior performance to SANTYL**, and **ease of use**, making it ideal for settings requiring patient and caregiver collaboration to improve adherence.



"I find it exciting due to the potential for improved clinical outcomes. It seems more practical for outpatient settings."
- **Reconstructive Surgeon, Acute Hospital**



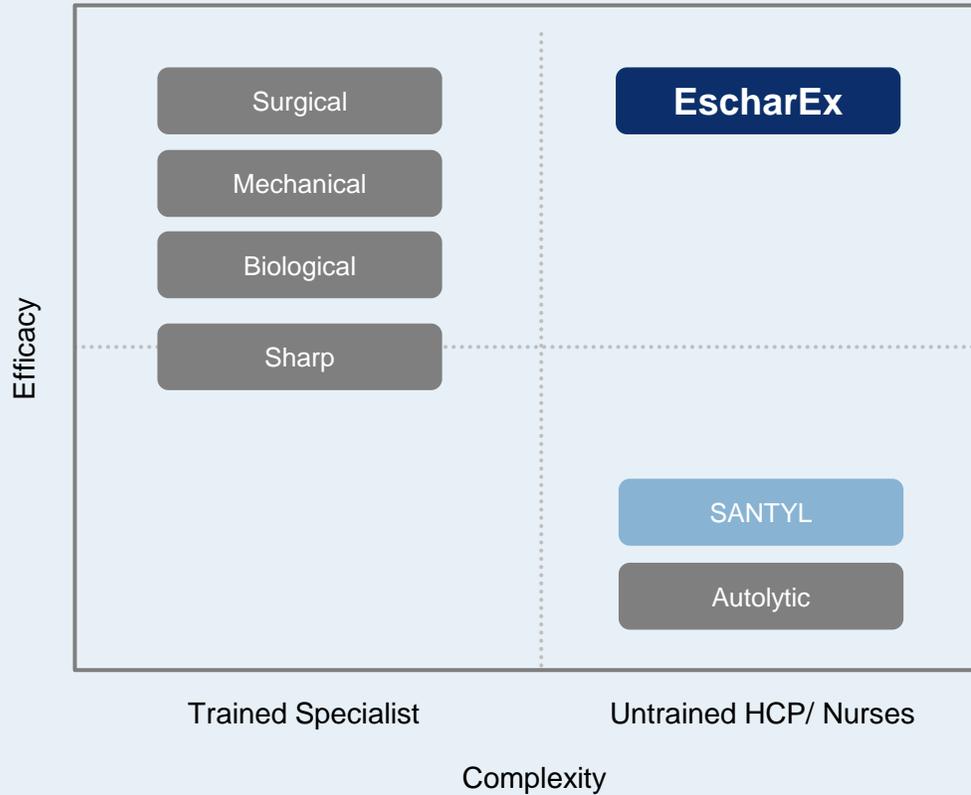
"I would replace SANTYL with this product for VLU patients, and substitute some autolytic and sharp debridement for DFU, since these wounds heal more slowly."
- **Surgeon, Medical Director, WCC**



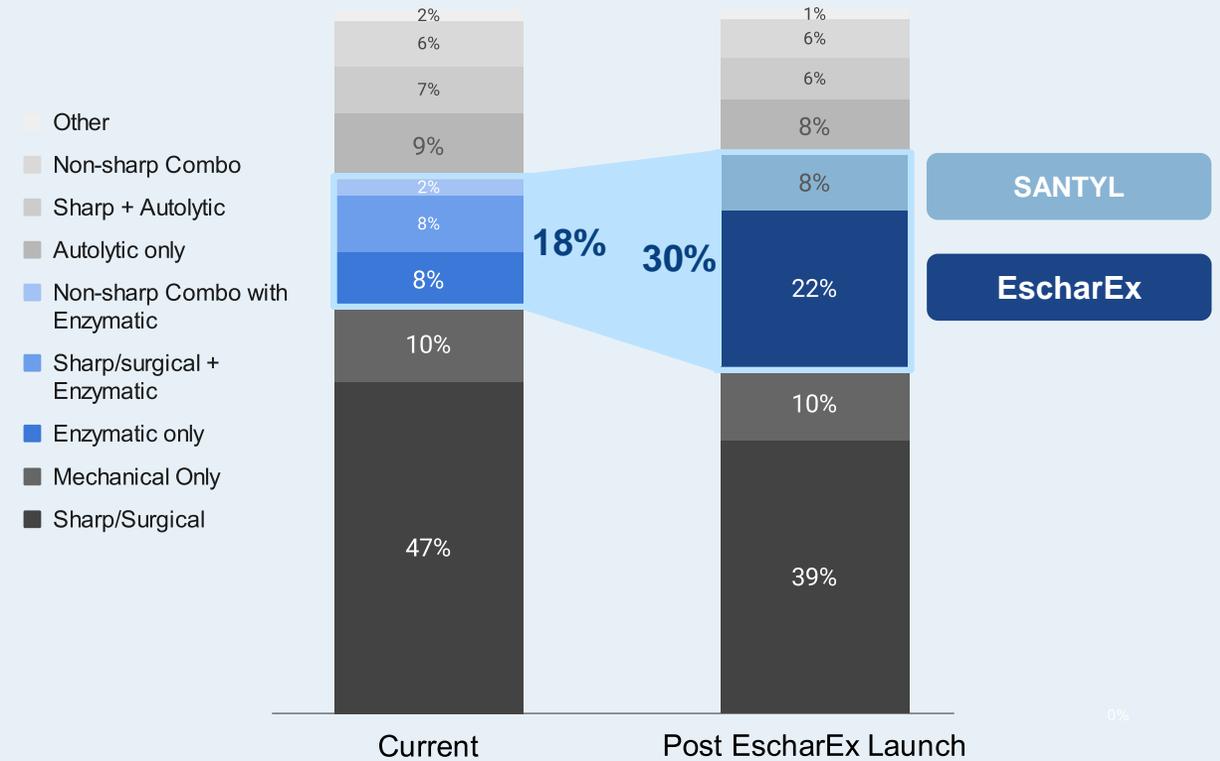
"A game changer in wound care, for shorter time for complete debridement and high efficacy. I'd use it as a First Line of Treatment when debriding, replacing all other modalities."
- **Nurse, SNF**

EscharEx Draws Share Across Debridement Modalities

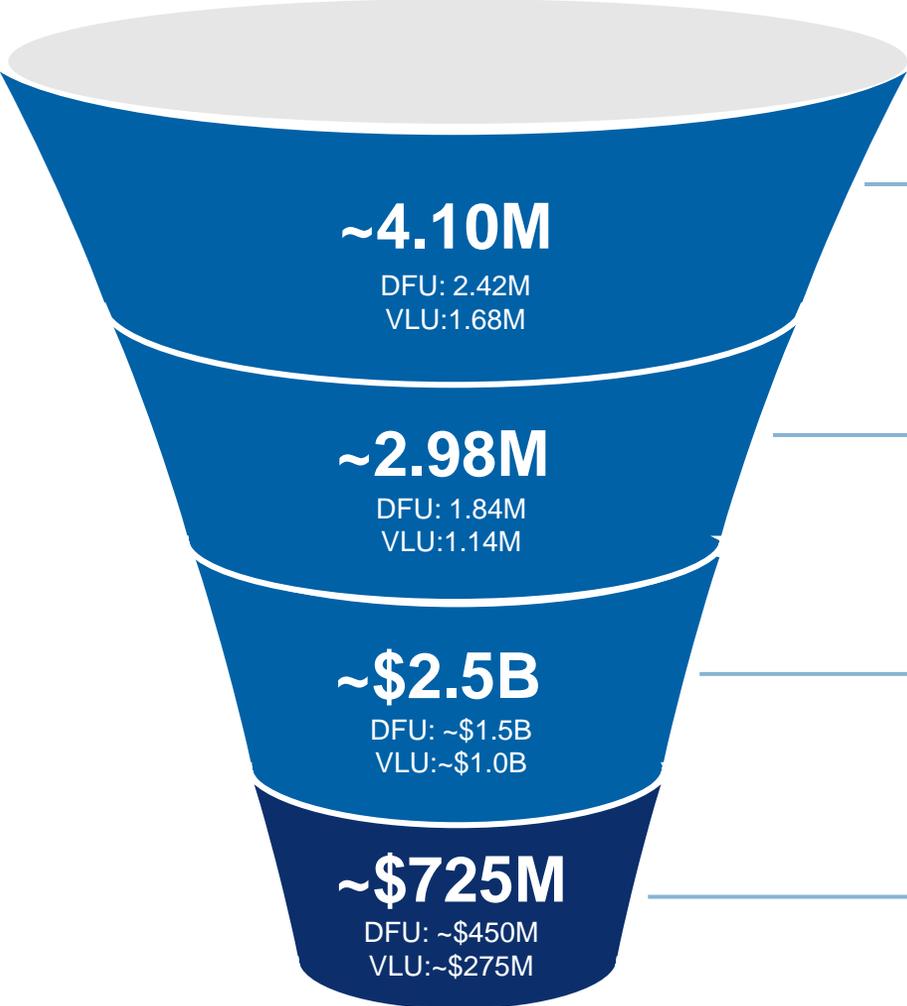
By delivering a highly effective and easy-to-use solution...



...and expanding the enzymatic debridement market as a whole



\$725M Projected Peak Sales in \$2.5B TAM in U.S.



2028 DFU & VLU Prevalence

Total patient population estimated through secondary research is **2.42M DFU patients** and **1.68M VLU patients** by 2028, for a **total of 4.10M**.

Patients Undergoing Debridement in 2028

Total patient population undergoing debridement has been quantified through a **survey and refined via qualitative interviews**, resulting in an overall **adjustment factor of 72%**. (76% of DFU, 68% of VLU).

2028 Total Addressable Market for Enzymatic Debridement

The total TAM for enzymatic debridement in the US has been calculated using an **average treatment cost of \$851 per patient**, resulting in a total **TAM of \$2.5 billion**.

Estimated Peak Sales of EscharEx in 2033

The peak **projected revenue** for **EscharEx** is approximately **\$725M**, based on an estimated **22.3% conversion rate** from current debridement techniques.



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EscharEx- An Exceptionally Attractive Commercial Opportunity

John C. Lantis II, MD

Site-Chief of Surgery, Mount Sinai West Hospital NY

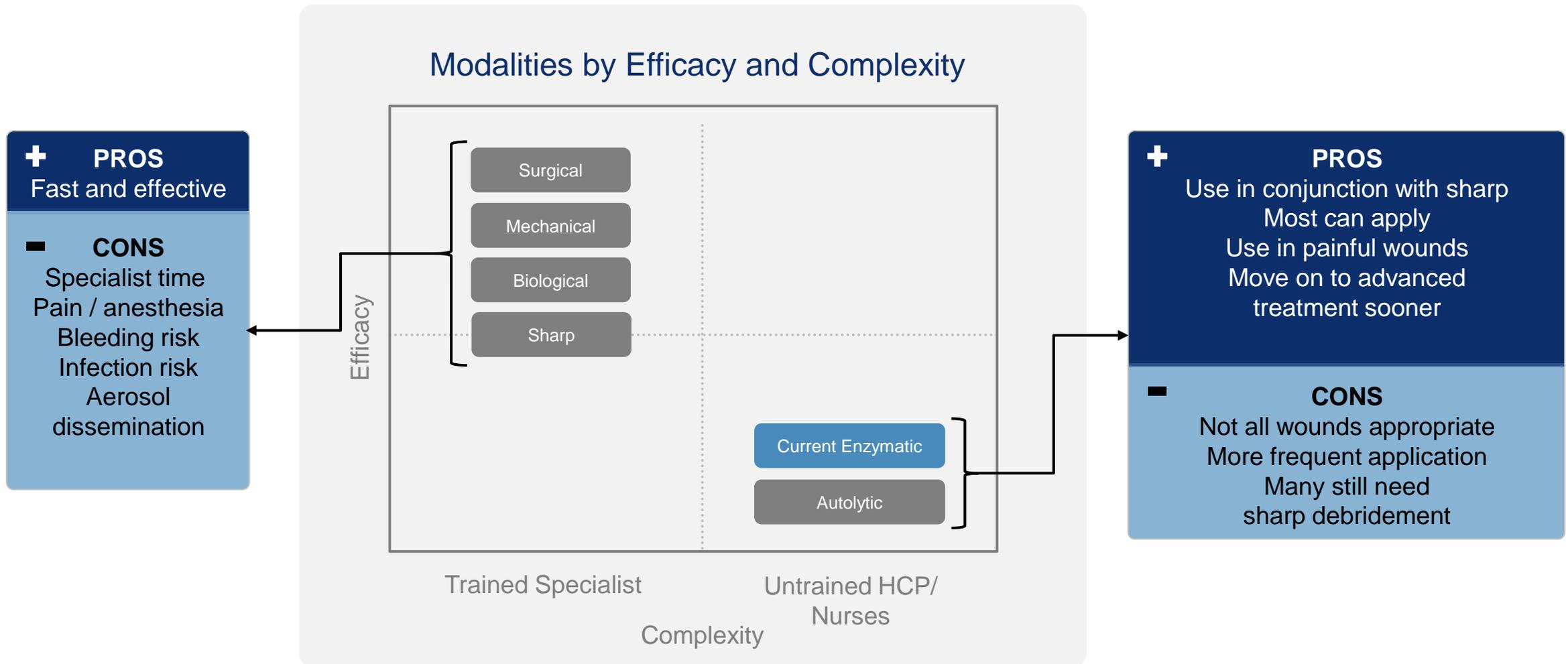
Professor of Surgery, Icahn School of Medicine at Mount Sinai

Principal Investigator on over 70 chronic wound and vascular surgery trials



John C. Lantis II, MD

Current Debridement Treatments are Sub-Optimal



EscharEx[®] Well-Positioned to Become Market Leader¹

EscharEx[®]



Investigational drug - Phase 3 expected to begin in 2H 2024

Mixture of enzymes; **multiple** targets of action

Debridement, promotion of granulation, reduction of biofilm & bacteria^{5,7}

1-2 weeks, daily; Monotherapy

Controlled Phase 2 trials; **significant superiority** over hydrogel & SOC⁶

Demonstrated to be safe and well-tolerated⁷

SANTYL[®]



Approved in the 1960s; \$375M+ annual revenues (2022)
Existing reimbursement code²

Collagenase; **single** target of action

Debridement⁸

4-8+ weeks, daily; typically coupled with sharp debridement³

*"There is a **lack of RCTs** with adequate methodological quality"*⁴

Demonstrated to be safe and well-tolerated

What Does the Data for SANTYL Show?



► Int Wound J. 2017 Apr 25;14(6):1055–1065. doi: [10.1111/iwj.12760](https://doi.org/10.1111/iwj.12760)

Enzymatic debridement with collagenase in wounds and ulcers: a systematic review and meta-analysis

[Jérôme Patry](#)^{1,2,3,✉}, [Virginie Blanchette](#)³

► [Author information](#) ► [Article notes](#) ► [Copyright and License information](#)

PMCID: PMC7950028 PMID: [28440050](https://pubmed.ncbi.nlm.nih.gov/28440050/)

CONCLUSION

This systematic review concludes that there is a ***lack of RCTs with adequate methodological quality regarding collagenase as an enzymatic debridement agent.*** Included studies had a ***high risk of bias*** with numerous and different outcomes. However, altogether, data reviewed support the use of collagenase for pressure ulcers and DFU and collagenase in conjunction with topical antibiotics in burns when enzymatic debridement is judged necessary in selected cases. Collagenase appears beneficial for wound healing and for its ability to remove necrotic or devitalised tissues. ***Even though studies have partially included chronic leg ulcers or venous leg ulcers, it is unclear if collagenase would be beneficial for that indication based on included studies.***

Other Drugs Approved for Debridement – A Comprehensive List:

- 1.

Why Do U.S. HCPs Prescribe SANTYL?

- **When sharp or surgical debridement isn't suitable**

Situations such as risk of pain, bleeding, infection, proximity to sensitive anatomical structures, lack of skilled professionals, suboptimal clinical settings, and patient preference make SANTYL an alternative

- **Slow, but effective**

While SANTYL acts more slowly, studies show it effectively debrides wounds over time

- **Reduced legal risk**

In the highly litigious U.S. healthcare environment, providers feel more secure using a prescription product

How Can EscharEx Disrupt this Market?

- **EscharEx is rapid, SANTYL is slow**

Faster debridement is preferred to help the wound convert from chronic state towards healing

In DFUs, rapid debridement is especially crucial, due to high risk of severe infections and other complications (hospitalization, amputation and sepsis)

EscharEx provides rapid debridement, with the majority of patients achieving this within 6-8 days

- **EscharEx has benefits beyond debridement**

Data show the ability of EscharEx to facilitate active wound closure

EscharEx has demonstrated antibacterial and anti-biofilm activity and supports the formation of healthy, highly vascular granulation tissue—all critical for effective healing

- **Reimbursement Policy**

Changes to Medicare policy further drives the desire to achieve complete WBP as quickly as possible



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Summary

EscharEx – A Clear Path to Success

- **Phase II data show robustness and consistency**
- **De-risked program: Phase III study designed for success**
- **DFU/VLU debridement represents an enormous market**
- **An incredible and unique commercial opportunity**

EscharEx Timelines

